CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

17-536/S-018

17-536/S-024

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW

1. ORGANIZATION
DDDP (HFD-540)

2. NDA NUMBER
17-536 ; 17-691;
17-781; 19-555

3. NAME & ADDRESS OF APPLICANT

Schering Corporation
Attention: Joseph F. Lamendola, Ph.D.
Vice President, U.S.Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

4. AF NUMBER

5. SUPPLEMENT(s)
NUMBER(s)DATE(s)
(SE5) for N 17-536/S024; N 17-691/S024;
N 17-781/S022; N 19-555/S016 dated 10//4 /00

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Diprosone (N 17-536) (N 17-781; N 7-691)	betamethsone dipropionate
Diprolene (N19-555)	betamethsone dipropionate

8. SUPPLEMENT(s) PROVIDES FOR:

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
S/A dated 5/31/00

SE5- Provides for labeling supplements for pediatric uses for the above drug products

10. PHARMACOLOGICAL
Anti-inflammatory Agent

11.HOW DISPENSED
xxx Rx OTC

12.RELATED CATEGORY
IND/NDA/DMF(s)

13. DOSAGE FORM(s)	14. POTENCY(ies)
N 17-536 (Cream)	0.05%
N 17-691 (Ointment)	0.05%
N 17-781 (Lotion)	0.05%
N 19-555 (Cream)	0.05%

15. **CHEMICAL NAME AND STRUCTURE**

m.w. .
CAS Registry No. - -

16. **RECORDS AND REPORTS**
CURRENT
X Yes No
REVIEWED
X Yes No

17. **COMMENTS**

The applicant submitted efficacy supplements on 10/4/00 to provide for the pediatric use for the above drug products. These supplements contained revised labeling to reflect this change. This labeling was reviewed from a technical standpoint and was found acceptable with the following exception:

(1) Under the section titled DESCRIPTION, we recommend that the USP declaration for the inactive ingredients be removed.
(2) The revised labeling did not contain of container labels in the supplements. It is assumed that this labeling is unchanged from a technical standpoint.

In addition, these supplements were amended on 5/31/01 to indicate the following information:

Chemistry, Manufacturing and Controls: Acceptable

The proposed changes in the efficacy supplement do not affect the CMCs as submitted in the NDA.

The applicant indicated that the currently marketed formulation was used in the individual studies for each NDA, and they do not plan to develop a pediatric formulation.

Environmental Impact: Acceptable

The firm claimed a categorical exclusion as required by 21 CFR 25.31 (a) as follows:

They indicated that the increase of active ingredient, betamethasone dipropionate, as the result of pediatric use does not increase the levels of aquatic contamination into the environment. The estimated concentration of active ingredient into the aquatic environment will be below 1 part per billion (ppb).

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue for this supplement. The PM should convey the information as requested under labeling (see paragraph 1 above under comments).

cc: Orig: NDAs 17-536 , 17-691, 17-781, and 19-555

HFD-540
HFD-540/Cook
HFD-540/Brown
HFD-520/Cintron
HFD-540/EGPappas
HFD-540/WHDeCamp:R/D initialed _

19. REVIEWER		
NAME	**SIGNATURE**	**DATE COMPLETED**
Ernest G. Pappas		06/18/01

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE